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09/977,579	10/15/2001	Peter Cox	674558-2001	1985

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EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/977,579	COX ET AL.	
	Examiner	Art Unit	
	Daniel Kolker	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-59* is/are pending in the application.

4a) Of the above claim(s) *44-48,50 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-43,49,51 and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *39-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/31/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's remarks and amendments filed 31 October 2005 have been entered. Claims 1 – 38 have been canceled; claims 39 – 59 are new.

2. Applicant is advised that the correct application number for this case is 09/977,579. The last two communications have contained typographical errors, mistakenly identifying it as 09/997,579.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Election/Restrictions

5. Newly submitted claims 44 – 48, 50, and 52 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims encompass nucleic acids encoding polypeptides at least 80% identical to SEQ ID NO:3, or at least 90% identical to SEQ ID NO:1. Applicant elected to prosecute the nucleic acid of SEQ ID NO:2 in the remarks filed 15 February 2005. As set forth on p. 2 of the office action mailed 29 April 2005, SEQ ID NO:2 is not a nucleic acid sequence. In a telephone conversation between Examiner Kolker and Angela Collison on 24 March 2005, applicant elected to prosecute SEQ ID NO:4, which is a nucleic acid sequence. Newly-presented claims 44 – 48, 50, and 52 encompass essentially the same subject matter as that encompassed by previously presented, and withdrawn, claims 4 – 9, 15, and 17. SEQ ID NO:4 has been searched in this case; other sequences have not been searched. Newly-presented claim 39 is drawn to a nucleic acid which encodes a protein at least 80% identical to SEQ ID NO:2; and dependent claims 40 – 43 make it clear that SEQ ID NO:4 is a member of this broad genus. As a courtesy to applicant, nucleic acid encoding SEQ ID NO:2 will also be searched in this case.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44 – 48, 50 and 52 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant is advised that claim 49 and those claims which depend from it are being examined to the extent they read on elected SEQ ID NO:4.

6. This application contains claims 44 – 48, 50, and 52 are drawn to an invention nonelected with traverse in the remarks filed 15 February 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

7. Claims 39 – 43, 49, 51, and 53 – 59 are under examination.

Objections and Rejections Necessitated by Amendment

Claim Objections

8. Claims 49, 53, 55, 56, and 59 are objected to because of the following informalities:

Claim 49 recites non-elected subject matter, including nucleic acid SEQ ID NO:3.

Claim 53 recites "a P3 subunit", whereas the majority of the application is drawn to beta-3 subunits.

Claims 55 and 56 depend from claim 65, but there is no claim 65. For the purposes of examination, the examiner assumes that the claims actually depend from claim 54, as new claims 54 – 56 appear to be similar to canceled claims 24 – 26.

Claim 59 appears to be grammatically incorrect; the verb "lyse" does not agree with other verbs in the claim. Amendment to "lysing" is recommended.

Appropriate correction is required.

9. Claim 51 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 51 encompasses nucleic acids which are complementary to stated sequences. This is a broader genus than the subject matter encompassed by claim 49, which does not include complementary sequences.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 encompasses nucleic acids complementary to SEQ ID NO:4. However the claim depends from claim 49 and thus the nucleic acids are required to encode a protein, but the complements will not encode a protein and thus the metes and bounds of the claim are unclear.

Withdrawn Rejections and Objections

12. The following rejections and objections made in the previous office action are withdrawn:

1) The objections to the figures and Brief Descriptions is withdrawn in light of the amendments.

2) The objection to claim 14 is withdrawn in light of the inclusion of SEQ ID NOs in the newly-presented claims.

3) The rejection under 35 USC § 101 and the corresponding rejection under § 112, first paragraph for lack of utility is withdrawn. The specification asserts that the claimed molecules are useful for a targets for drugs to treat pain (p. 4 lines 20 – 24). This was also asserted in the previously-filed international application (PCT/EP00/01783 p. 4 lines 1 – 4) and the provisional application (60/129473, p. 3 line 31 – p. 4 line 4).

New claim 39 encompasses a nucleic acid which encodes SEQ ID NO:2. The specification discloses (p. 15 line 29 – p. 16 line 2) that SEQ ID NO:2 is the human beta-3 polypeptide sequence. Morgan et al. (2000. Proc Natl Acad Sci USA 97:2308-2313, cited on IDS filed 15 October 2001) teaches the human sequence, EMBL accession number AJ243396, as well as the rat sequence, EMBL AJ243395 (see bottom of p. 2308). These correspond to NCBI accession numbers HSA243396 and RNO243395, respectively. When back-translated to nucleic acid, SEQ ID NO:2 is identical to nucleotides 376 – 1020 of HSA243396 and is 98.3% identical to RNO243395. Shah (2000, cited by applicant on IDS filed 31 October 2005) teaches that the results of experiments using the rat sequence (see p. 3985, final paragraph), wherein expression of the nucleic acid is increased in an art-accepted model of pain. Given the close homology between the rat and human sequences at the nucleic acid levels, the examiner concedes that the specification as filed discloses a specific and substantial asserted utility.

4) The rejection of claims 1 – 3, 10 – 14, 16, 20, and 24 – 28 under the judicially created doctrine of obviousness-type double patenting is withdrawn. The claims currently pending in that case are drawn to a patentably distinct invention.

Maintained Rejections and Objections

Claim Rejections - 35 USC § 112

13. Claims 39 – 43, 49, 51, and 53 – 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:4, does not reasonably provide enablement for all nucleic acids which encode any fragment, of unspecified length, of SEQ ID NO:2, nor for the broad genera of nucleic acids at least 10 consecutive nucleotides long. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (FED. Cir. 1988).

Claim 39 encompasses a broad genus of nucleic acids. Not only does the claim encompass any nucleic acid encoding SEQ ID NO:2, but it also encompasses nucleic acids which encode proteins at least 80% thereto, as well as nucleic acids which are at least 80% identical to any peptide fragment of SEQ ID NO:2. While the claim requires that the beta-3 subunit of SEQ ID NO:2 or the fragment "co-operates with at least one" alpha subunit of a sodium channel, the term "co-operates" is extremely broad. While several terms are explicitly defined in the specification (see, for example, p. 8 line 29 – p. 9 line 28), "co-operates" is not among them. Thus in the absence of an explicit definition in the specification, it is appropriate to turn to other sources. Alberts et al. (1994. Molecular Biology of the Cell, p. G-7) define cooperativity as follows:

> Phenomenon in which the binding of one ligand molecule to a target molecule promotes the binding of successive ligand molecules. Seen in the assembly of large complexes, as well as in enzymes and receptors composed of multiple allosteric subunits, where it sharpens the response to a ligand.

Thus as defined in the art, the term appears to mean that one molecule's presence increases the function of another molecule. The specification discloses (pp. 49 – 52) the results of an experiment in which the presence of the rat beta-3 subunit polypeptide (although not stated as

such in these pages, presumably SEQ ID NO:1, which is encoded by SEQ ID NO:3; see p. 15 lines 25 – 28 and p. 8 lines 3 – 8) leads to a higher percentage of channels in the fast mode, and changes in the inactivation kinetics of the sodium channel. See Table 2, p. 52 of the specification. Thus it appears that the rat polypeptide is capable of cooperating with an alpha subunit.

However, claim 39 as written encompasses nucleic acids which encode a protein at least 80% identical to any fragment of SEQ ID NO:2. There is no requirement that any particular region of the encoded protein be preserved. There are no working examples of peptide fragments which allow for the degree of cooperativity seen in Table 2 of the specification. For that matter, there are no working examples showing that any fragment is capable of such cooperativity. As dependent claims 41 – 43 allow for any portion of SEQ ID NO:4 from bases 1 – 1261 to be included, (i.e the entire coding region of the nucleic acid; see specification p. 8 lines 13 – 18) there is insufficient guidance in the disclosure as to which regions of the resultant protein are important.

Given that the claims encompass variants with as little as 80% sequence identity (claim 39) or 90% sequence identity to either the entirety of SEQ ID NO:4 or a specifc fragment (claims 40 and 42), and that the only working example in the specification is with the rat sequence, which is 98% identical to human, and that there are no working examples of nucleic acids encoding fragments, and finally that there is no requirement that any particular region of the resultant protein be preserved, it would take undue experimentation on the part of a skilled artisan to be able to make and use the nucleic acids of claims 39 – 43 commensurate in scope with the claims.

With respect to claim 49, the claims reads on any ten consecutive nucleotides of SEQ ID NO:4. The claim requires that the polypeptide encoded by the nucleotides be able to cooperate with an alpha subunit. However, as with claim 39, there is no requirement that any particular region of the encoded protein be preserved. The claims encompass an unreasonable number of possible sequences for which the claimed functions have not been demonstrated. There are no working examples of nucleic acids as short as ten nucleotides which have the recited properties, and the specification does not provide sufficient guidance to the artisan as to how to make these nucleic acids. Since cooperativity is a very broad term, not explicitly defined by applicant, which includes such features as modulating ligand-binding properties, it would take

undue experimentation in order for a skilled artisan to make and use the very broad claimed genera.

Similarly, claims 53 and 54 encompass kits with nucleic acids of any length, as long as the nucleic acids can hybridize to a nucleic acid encompassed within claim 39. There is no requirement for minimum length for the primers, nor is there a requirement that they be able to bind under any particular hybridization or washing conditions. It is noted that claims that recite hybridization language are indefinite (see the rejection under 35 U.S.C. § 112, second paragraph, below), and do not recite that the nucleic acid encode a protein. While claims 53 and 54 depend from claim 39, that claim only requires that a fragment of unspecified size or identity be encoded.

The term "hybridize" or "hybridization" generically refers to a process in which a strand of nucleic acid joins or matches up with a complementary strand through the process of base pairing, wherein the process is basically used to locate or identify DNAs encoding specific proteins. It is well established in the art that 15-20 bases have been considered sufficient to achieve this process. Strauss (1993. Current Protocols in Molecular Biology 6.3.1 - 6.3.6) teaches that the "[t]emperature and salt concentration dramatically affect the maintenance of specific hybrids. Detergents and other charged species can have a profound effect upon the nonspecific binding of species that contribute to background" (see p. 6.3.5, first column, second paragraph). With these points in mind, it is the Examiner's position that giving the claims their broadest reasonable interpretation, this language reads on an infinite number of possible DNA sequences for which there is not sufficient enablement.

Claim 51 encompasses sequences which are complementary to any ten nucleotides of SEQ ID NO:4, but as the claim depends from claim 49, it necessarily incorporates the limitations of the parent claim. Thus the nucleic acids of claim 51 are required to encode a polypeptide with the properties recited in claim 49, but those nucleic acids which are complementary to SEQ ID NO:4 will not encode a protein that has the properties; in fact it is likely they will either encode a protein with a very different function, if it has a function at all.

In the previous office action, the examiner had raised the issue that the term "amplification primers", recited in current claim 53, might be overly broad. Applicant's arguments on p. 11 of the remarks (final paragraph) are convincing on this point.

Applicant argues, on p. 11 of the remarks, that pp. 11 – 15 of the specification provide ample guidance as to which portions of the proteins should be preserved when the claims read

on nucleic acids which encode proteins or protein fragments. Applicant's arguments have been fully considered but are not persuasive. The examiner concedes that these pages do in fact point out certain regions of the protein encoded by SEQ ID NO:4. However, there is no evidence that any of the cited regions have the claimed properties. In fact, the skilled artisan would have reason to doubt that certain regions cited in the text in fact have these properties. For example, the signal sequences, which are cleaved off in processing of the protein, are cited as preferred fragments (p. 17 lines 6 – 17). It seems highly unlikely that these amino acids are involved in coooperativity, as Figure 4 indicates they are cleaved away from the rest of the protein. Page 18, first complete paragraph, does provide guidance to the artisan as to how to test whether two proteins interact, but this does not constitute sufficient guidance for enablement of the claimed invention. Physical interaction may be necessary for cooperativity, but there is no reason to believe it would be sufficient. For example, antibodies would be expected to physically interact with their target protein, but clearly this does not constitute cooperativity. Given the breadth of the claimed invention, the lack of guidance as to which regions of the proteins encoded by the claimed nucleic acids should be included, and the large degree of experimentation required on the part of the skilled artisan, an undue degree of experimentation would be necessary to make and use the invention commensurate in scope with the claims.

In the previous office action, the examiner indicated that the claims were not enabled over their full scope as the broadest reasonable interpretation of "host cell" included cells residing in a human body that had been transformed by gene therapy. Applicant's new claim 58 to read "an isolated recombinant cell" is sufficient to overcome this aspect of the rejection. However since the cell comprises the nucleic acid of claim 39, which stands rejected for the reasons set forth above, claim 58 is rejected.

14. Claims 29 – 43, 49, 51, and 53 – 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection is maintained for the reasons made of record previously and explained in further detail below. Applicant argues, on p. 12 of the remarks, that the claims are adequately supported by the specification. Applicant's arguments have been fully considered but are not

persuasive. To the extent that the claims encompass nucleic acids which encode protein variants which differ by as much as 20% from SEQ ID NO:2, the specification clearly does not support this broad genus. SEQ ID NO:1 and 2 are 98% identical (specification, p. 16, first complete paragraph). The specification provides adequate written description of the genus of nucleic acids which encode proteins at least 98% identical to SEQ ID NO:2, wherein the protein cooperates with at least one alpha subunit of a voltage-gated sodium channel. However the specification does not provide evidence that the inventor was in possession of the considerably broader genus, i.e. wherein the protein is only 80% identical.

Furthermore, claim 39 encompasses nucleic acids which encode any peptide fragment which has the cooperativity properties recited. The specification does not provide evidence of said fragments. While there is general speculation as to which regions might have certain structural features (see pp. 15 – 19), none of those regions are shown to be, or even hypothesized to be, the co-operativity-specific regions. The specification does not provide evidence of possession of the nucleic acids encoding the claimed fragments. Claim 39 also encompasses nucleic acid sequences complementary to said fragments. Since the genus of fragments is not sufficiently described, the same is necessarily true of the complements.

Claim 49 encompasses nucleic acids at least 10 consecutive nucleotides long. Again, this is a very broad genus which has not been adequately described. While the claim reads on SEQ ID NO:4, which encodes SEQ ID NO:2, it also reads on many more nucleic acids than that which have not been described.

Claims 53 and 54 encompass nucleic acids which can hybridize to the nucleic acids of SEQ ID NO:39. As the base claim is not adequately described, these claims also are not adequately described. Furthermore, since these claims do not recite any hybridization or washing conditions, they merely require that the primers or probes be capable of hybridizing. As the genus of primers and probes which can hybridize is essentially infinite, these claims have not been adequately described.

Thus contrary to applicant's arguments, the claims as written are very broad and are not supported by the specification.

Claim Rejections - 35 USC §§ 102 and 103

15. Claims 39, 49, 51, and 54 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fleishmann et al. (U.S. Patent 6,294,328, issued 25 September 2001, filed 24 June 1998; cited in previous office action).

In the previous office action Fleishmann was cited as prior art over claims 14, 16, and 24. These claims have been canceled, but are similar to pending claims 49, 51, and 54. Claim 49 encompasses nucleic acids at least 10 nucleotides in length which encode proteins with certain properties. Fleishmann et al. teach SEQ ID NO:2. Nucleotides 7364 – 7383 of Fleishmann et al. are complementary to nucleotides 500 – 519 of instantly claimed SEQ ID NO:4. Because the prior art sequence is complementary to the claimed sequence, the two will inherently hybridize under stringent conditions. While applicant has provided a definition of stringent conditions on p. 11 of the specification, that definition is exemplary, not limiting, and thus the term can include conditions of any stringency. Therefore the prior art sequence meets the hybridization of claim 54.

Applicant argues that the claims as currently presented are distinguishable over the prior art because the nucleic acid sequences must match over the entire length. Applicant's arguments have been fully considered but are not persuasive. Claim 39 includes the limitation "or with a peptide fragment thereof, or a sequence complementary thereto", and further requires certain functional properties of the encoded polypeptide or fragment. The claim does not require identity over the entire coding region. Similarly claim 51 recites "a sequence complementary thereto"; it does not require identity over the full-length sequence.

The examiner is unable to determine if the prior art products inherently have the cooperativity properties recited in claims 39 and 49. However when the prior art teaches products that meet the structural limitations of a claimed product but are silent as to inherent characteristics, rejections under 102/103 are proper. See MPEP § 2112(III). Furthermore, in this case there are no features of the full-length sequence which are disclosed as being either necessary or sufficient to provide the properties.

16. Claims 39, 49, 51, 53 – 54, 56 – 59 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lovenberg et al. (U.S. Patent 6,723,841, issued 20 April 2004, effective filing date 7 June 1995; cited in previous office action).

This rejection is maintained for the reasons made of record in the previous office action. Briefly, bases 95 – 113 of Lovenberg's SEQ ID NO:3 are identical to bases 72 – 90 of

applicant's SEQ ID NO:4. Applicant argues that the claims as currently presented are distinguishable over the prior art because the nucleic acid sequences must match over the entire length. Applicant's arguments have been fully considered but are not persuasive. Claim 39 includes the limitation "or with a peptide fragment thereof, or a sequence complementary thereto", and further requires certain functional properties of the encoded polypeptide or fragment. The claim does not require identity over the entire coding region. Similarly claim 51 recites "a sequence complementary thereto"; it does not require identity over the full-length sequence.

The examiner is unable to determine if the prior art products inherently have the cooperativity properties recited in claims 39 and 49. However when the prior art teaches products that meet the structural limitations of a claimed product but are silent as to inherent characteristics, rejections under 102/103 are proper. See MPEP § 2112(III). Furthermore, in this case there are no features of the full-length sequence which are disclosed as being either necessary or sufficient to provide the properties.

17. Claims 39, 49, 51, 54 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GenBank Locus D44825.

This rejection is maintained for the reasons made of record in the previous office action. Bases 33 – 170 of D44825 are 100% identical to bases 1044 – 1181 of instantly claimed SEQ ID NO:4, and bases 172 – 248 of D44825 are 100% identical to bases 1183 – 1259 of SEQ ID NO:4. Applicant argues that the claims as currently presented are distinguishable over the prior art because the nucleic acid sequences must match over the entire length. Applicant's arguments have been fully considered but are not persuasive. Claim 39 includes the limitation "or with a peptide fragment thereof, or a sequence complementary thereto", and further requires certain functional properties of the encoded polypeptide or fragment. The claim does not require identity over the entire coding region. Similarly claim 51 recites "a sequence complementary thereto"; it does not require identity over the full-length sequence.

The examiner is unable to determine if the prior art products inherently have the cooperativity properties recited in claims 39 and 49. However when the prior art teaches products that meet the structural limitations of a claimed product but are silent as to inherent characteristics, rejections under 102/103 are proper. See MPEP § 2112(III). Furthermore, in this case there are no features of the full-length sequence which are disclosed as being either necessary or sufficient to provide the properties.

18. Claims 39 – 43, 51, 53 – 54 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stratagene random primers, 1991 catalog, p. 66 (cited in previous office action).

This rejection is maintained for the reasons made of record previously. The random primers are capable of hybridizing to all known sequences. Applicant argues that the claims as currently presented are distinguishable over the prior art because the nucleic acid sequences must match over the entire length. Applicant's arguments have been fully considered but are not persuasive. Claim 39 includes the limitation "or with a peptide fragment thereof, or a sequence complementary thereto", and further requires certain functional properties of the encoded polypeptide or fragment. The claim does not require identity over the entire coding region. Similarly claim 51 recites "a sequence complementary thereto"; it does not require identity over the full-length sequence.

The examiner is unable to determine if the prior art products inherently have the cooperativity properties recited in claims 39 and 49. However when the prior art teaches products that meet the structural limitations of a claimed product but are silent as to inherent characteristics, rejections under 102/103 are proper. See MPEP § 2112(III). Furthermore, in this case there are no features of the full-length sequence which are disclosed as being either necessary or sufficient to provide the properties.

19. Claims 39 – 43, 51, 53 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Fleishmann et al. in view of Brown et al. (U.S. Patent 5,807,522, issued 15 September 1998, filed 7 June 1995; cited in previous office action), or in the alternative Lovenberg et al. in view of Brown et al., or in the alternative D44825 in view of Brown et al., or in the alternative Stratagene in view of Brown et al. This rejection is maintained for the reasons made of record in the previous office action. Applicant traversed the rejection by arguing that Fleishmann, Lovenberg, Genbank, and Stratagene do not anticipate the claimed inventions. Applicant's arguments are not persuasive as detailed in the previous paragraphs. Applicant did not traverse the propriety of the rejection under § 103 as being obvious over Brown, and as each of the references is prior art under § 102, the rejection under § 103 stands for the reasons of record.

Conclusion

20. No claim is allowed.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.
January 17, 2006

SHARON TURNER, PH.D.
PRIMARY EXAMINER
1-17-06